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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/512,363	02/23/00	NI J	PF396P1

HM12/0402

Human Genome Sciences Inc
9410 Key West Avenue
Rockville MD 20878

EXAMINER	
HOLLERAN, A	
ART UNIT	PAPER NUMBER
1642	6

DATE MAILED: 04/02/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.	Applicant(s)
09/512,363	Ni et al
Examiner	**Group Art Unit**
Anne Holleran	1642

☐ Responsive to communication(s) filed on _____

☐ This action is **FINAL.**

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 1 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claim

☒ Claim(s) 1-18 is/are pending in the applicat

Of the above, claim(s) _____ is/are withdrawn from consideration

☐ Claim(s) _____ is/are allowed.

☐ Claim(s) _____ is/are rejected.

☐ Claim(s) _____ is/are objected to.

☒ Claims 1-18 are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☒ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____ .

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

— SEE OFFICE ACTION ON THE FOLLOWING PAGES —

DETAILED ACTION

Election/Restriction

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-13, drawn to nucleic acids, method of making vectors, vectors, method of making host cells, host cells, method of making a polypeptide, classified in class 536, subclass 23.5.

II. Claim 14, drawn to polypeptides, classified in class 530, subclass 350.

III. Claim 15, drawn to antibodies, classified in class 530, subclass 387.1.

IV. Claim 16 and 17, drawn to methods of treatment, classified in class 514, subclass 2.

V. Claim 18, drawn to methods of screening for agonists and antagonists, classified in class 435, subclass 4.

2. The inventions are distinct, each from the other, for the following reasons:

Although there are no provisions under the section for "Relationship of Inventions" in MPEP 806.05 for inventive groups that are directed to different products, restriction is deemed to be proper because these products constitute apparently distinct inventions for the following reasons: the polynucleotides of group I, the polypeptides of group II and the antibodies of group III are chemically distinct products unrelated in sequence and separately classified, having separate fields of search. Other than the fact that polypeptides and polynucleotides are derived

from the same cell type, the polynucleotides of group I and the polypeptides of group II have no relationship to each other structurally and no chemical structural relationship to the antibodies of group III. The products of groups I and II can be independently synthesized by chemical means. An antibody is encoded by an entirely different DNA than that of the protein which is bound by that antibody, and the primary sequence of the antibody bears no relationship to the sequence of the detected protein. Each of the products has separate and unrelated uses and are not disclosed as being capable of use together. Further, it would place undue burden on the examiner to examine several independent inventions in one application.

Inventions II and IV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the polypeptides of group II can be used in a method of making an antibody or in a method of screening for reactive antibodies, which are process which are materially different from methods of treatment.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

3. The claims of groups I, II and III are each drawn to separate and distinct products relating to separate and distinct polypeptides. In claim 1, the product claims are in improper Markush

format (see **Ex parte Markush**, 1925 C.D. 126 and **In re Weber**, 198 USPQ 334). Each of the different polypeptides is separate and distinct because each has a separate and distinct primary sequence. Group I encompasses nucleic acids encoding separate and distinct polypeptides and group III encompasses antibodies specific for separate and distinct polypeptides. Each of the polypeptides, TR11, TR11SV1 and TR11SV2, is not a member of a single genus of invention, but constitutes an independent and patentably distinct invention. Accordingly, these claims are subject to restriction under 35 U.S.C. 121.

Upon election of groups I, II or III, Applicant is additionally required to elect a single species. In the case of group I, Applicant is required to elect polynucleotides encoding a single polypeptide. In the case of group II, Applicant is required to elect a single polypeptide. In the case of group III, Applicant is required to elect antibodies binding to a single polypeptide. This requirement is not to be construed as a requirement for an election of species, since each of the polypeptides recited in alternative form is not a member of a single genus of invention, but constitutes an independent and patentably distinct invention.

4. Applicant is advised that the reply to this requirement, to be complete, must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any

amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(I).

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Anne Holleran, Ph.D. whose telephone number is (703) 308-8892. Examiner Holleran can normally be reached Monday through Friday, 9:00 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa, Ph.D. can be reached at (703) 308-3995.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist at telephone number (703) 308-0196.

Anne L. Holleran
Patent Examiner
March 29, 2001

GEETHA P. BANSAL
PRIMARY EXAMINER